

REMARKS

Claims 22-29 are pending.

Double Patenting Rejection

Claims 22-29 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-9 of U.S. Patent No. 6,224,579 to Modak et al. The Examiner indicates that the conflicting claims are not identical, but are not allegedly patentably distinct from each other because the claims of the present application are broader than the claims of the parent patent.

Upon the allowance of a currently pending claim, Applicants will submit a terminal disclaimer. Applicants note that the filing of a disclaimer is not an admission of the propriety of the rejection of these claims. *See Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991).

The Rejections under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 22-29 have been rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,567,495 to Modak et al. (hereinafter “the ‘495 patent”). The Examiner alleges that it is *prima facie* obvious to eliminate an object (chlorhexidine) and its function (antimicrobial effect) in the absence of a showing of criticality. The Examiner alleges that the Applicant has done no more than eliminate chlorhexidine in view of the fact that it may be irritating to a patient, which does not result in an unexpected and nonobvious invention. Applicants respectfully traverse the rejection.

The present invention is directed to an anti-infective article prepared by exposing the article to a treatment solution comprising a metal compound, triclosan and hydrogel, *without the addition of chlorhexidine or a chlorhexidine salt*. The combination of triclosan and a metal, such as silver, in the present invention confers an unexpected synergistic antimicrobial effect (See, e.g., specification, page 21, line 1 to page 23, line 26). The reduction in bacterial cell growth due to the combination of triclosan and silver far exceeds the expected reduction as caused by each component alone, as well as the additive effect of the two components together (Tables 3 and 4). Although the '495 patent discloses the use of triclosan, it fails to appreciate the synergistic effect of the triclosan and silver, as disclosed in the present invention. Triclosan is not even used as a component in any of the disclosed compositions or examples and is merely listed as suitable anti-infective agent (col. 7, line 44). The specification of the '495 patent fails to apprise the skilled artisan of the unexpected results achieved with the combination of triclosan and silver.

Therefore, Applicants submit that the '495 patent does not render the present invention obvious.

In contrast to the present invention, the '495 patent is concerned with an anti-infective medical device that is coated at various portals of entry into the device with an anti-infective agent, merely citing agents such as, chlorhexidine, triclosan, and silver, among a laundry list of many other candidate agents. The '495 patent fails to disclose each and every required element of the present invention, i.e. metal compound, triclosan and hydrogel, *without chlorhexidine*. Therefore, the '495 patent does not sufficiently to render the pending claims obvious.

The '495 specification also provides no motivation to one of skill in the art to remove chlorhexidine from the composition used to impregnate medical devices. In fact, *every* example disclosed in the '495 specification contains chlorhexidine acetate. There is no suggestion provided in '495 that would encourage the skilled artisan to avoid using chlorhexidine in medical

devices. Without such a teaching or suggestion, the '495 patent does not render the claimed invention obvious.

Although reports of chlorhexidine reactions have been reported, it is a commonly used wide-spectrum antiinfective agent. The skilled artisan would be aware of the possibility for adverse reactions for some users. However, its superior efficacy as an antiinfective agent balanced with the few cases reported would certainly not deter the skilled artisan from its use and would not provide sufficient motivation for one of skill in the art to avoid using chlorhexidine at the time of the invention. Taken together, the '495 specification and the knowledge of the skilled artisan would not provide any motivation for designing a composition that lacks chlorhexidine. Therefore, the presently claimed composition is not obvious.

For the foregoing reasons, Applicants submit that claims 22-29 are not unpatentable over the '495 patent and respectfully request withdrawal of the rejection of the claims.

Claims 22-29 have also been rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over US Patent No. 6,093,414 to Christopher Capelli (hereinafter "the '414 patent"). The Examiner alleges that the '414 patent concerns the use of silver-based antimicrobial compositions for application to a polymer matrix or to the surface of dressing, or as a topical composition. The Examiner contends that the '414 patent contemplates multiple uses of this composition and that a medical article, prepared with it, would be obvious. Applicants respectfully traverse the rejection.

The '414 patent fails to disclose the synergistic effects of silver and triclosan. Example 23 only discloses the combination of silver (2%) and triclosan (2%) for use as a topical composition and does not show any data regarding the stability or efficacy of the disclosed composition on microbial growth or adherence. Not only is there no data, there is no teaching

provided that would suggest to one of skill in the art of the unexpected benefits of the combination of silver and triclosan in a treatment solution for medical articles. Since the present specification discloses unexpected synergistic effects and the '414 patent fails to suggest such effects, Applicants submit that the '414 patent does not render the present invention obvious. Therefore, Applicants submit that claims 22-29 are not unpatentable over the '414 patent and respectfully request withdrawal of the rejection of claims 22-29.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that claims 22-29 constitute allowable subject matter and respectfully request withdrawal of the outstanding rejections and allowance of the claims.

Applicants request a two month extension of time and enclose herewith the requisite fee as set forth in 37 C.F.R. § 1.17(a)(2). Applicants do not believe that any additional fee is required in connection with the submission of this document. However, should any fee be required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this sheet is enclosed.

Respectfully submitted,



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